



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,621	12/21/2001	Walter Callen	D1350-6US	9848
29062	7590	12/26/2008	EXAMINER	
VERENIUM CORPORATION			HUTSON, RICHARD G	
Intellectual Property Department			ART UNIT	PAPER NUMBER
P.O. Box 910550			1652	
SAN DIEGO, CA 92191-0550				
			MAIL DATE	DELIVERY MODE
			12/26/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/034,621	CALLEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 September 2008.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-7,9-12,16,28-44,46-49,51-53 and 55 is/are pending in the application.
- 4a) Of the above claim(s) 34,35,38 and 44 is/are withdrawn from consideration.
- 5) Claim(s) 12 and 16 is/are allowed.
- 6) Claim(s) 1-7,9-11,28-33,36,37,39-43,46-49,51-53 and 55 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Applicant's amendment of claim 1, 3-5, 9, 10, 12, 16, 31, 46, 51 and 52, in the paper of 9/3/2008, is acknowledged. Claims 1-7, 9-12, 16, 28-44, 46-49, 51-53 and 55 are still at issue and are present for examination.

Applicants' arguments filed on 9/3/2008 have been fully considered and are deemed to be persuasive to overcome some of the /rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 34, 35, 38 and 44 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Interview request***

Applicants comments regarding an interview request made in the response submitted on 9/3/2008 is acknowledged. It is pointed out to applicants that as per MPEP Section 713, "When applicant is initiating a request for an interview, an "Applicant Initiated Interview Request" form (PTOL-413A) should be submitted to the examiner prior to the interview in order to permit the examiner to prepare in advance for the interview and to focus on the issues to be discussed. This form should identify the participants of the interview, the proposed date of the interview, whether the interview will be personal, telephonic, or video conference, and should include a brief description of the issues to be discussed.

It is noted that a voice mail was left for applicant's representative at 858-526-0376, after an initial review of the instant response, but such did not lead to any discussion prior to the mailing of the instant office action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-11, 28-33, 36, 37, 39-43, 46-49, 51-53 and 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid comprising SEQ ID NO: 1 and encoding a polypeptide having polymerase activity, does not reasonably provide enablement for any nucleic acid comprising a sequence that encodes a polypeptide having polymerase activity wherein the sequence comprises a mere 100 consecutive bases of the sequence set forth in SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 11-7, 9-11, 28-33, 36, 37, 39-43, 46-49, 51-53 and 55. In response to this previous rejection, applicants have amended claims 1, 3-5, 9, 10, 12, 16, 31, 46, 51 and 52 and traverse the rejection as it applies to the newly amended claims.

Applicants continue to traverse this rejection as previously on the basis that applicant's instant amendment addresses the issues with regard to enablement .

Applicants submit that after entry of this amendment, the claims will be directed to (a) those nucleic acids with at least 95% sequence identity to SEQ ID NO: 1 that encode polypeptides having polymerase activity, (b) nucleic acids that encode polypeptides having polymerase activity that are enzymatically active fragments of the polypeptides of (a), or sequences that are fully complementary to the full length of (a) or (b).

Applicant's amendment and complete argument is acknowledged and has been carefully considered, however, is not found persuasive for the reasons previously made of record and repeated herein.

It remains that the breadth of applicants claimed genus of nucleic acids continues to lack enablement for those nucleic acids which merely encode enzymatically active fragments of those polypeptides encoded by a nucleic acid having 95% sequence identity to SEQ ID NO: 1 (portion a of claim 1). While applicants stipulate that these nucleic acids encode a polypeptide that has polymerase activity, the claimed nucleic acids are not limited to encoding those fragments of those nucleic acids having 95% sequence identity to SEQ ID NO: 1, that have polymerase activity, but rather those fragments of those nucleic acids having 95% sequence identity to SEQ ID NO: 1, that are enzymatically active. Thus the only structural/functional relationship between the sequences of (b) and (a) are that the sequences of (b) encode an enzymatically active fragment of (a). The genus of those nucleic acids encoding enzymatically active

fragments of a polypeptide encoded by a nucleic acid having 95% identity to SEQ ID NO: 1 remains to be enabled for the reasons previously stated.

The maintenance of this rejection is considered appropriate as the polypeptides encoded by those nucleic acids which have 95% sequence identity to the SEQ ID NO: 1 encompass a great many enzymatic activities in addition to polymerase activity. At the very least polymerases themselves comprise polymerase activity, 3'-5' exonuclease activity, 5'-3' exonuclease activity, nucleotide binding activity and template binding activity.

Because of this lack of guidance, and the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired enzymatic activity and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require undue experimentation for one skilled in the art to arrive at the majority of those polypeptides of the claimed genus defined merely as all nucleic acids having at the claimed identity to SEQ ID NO: 1 and encoding a polypeptide having any enzymatic activity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including those nucleic acids comprising a sequence which encodes a polypeptide which has any enzymatic activity of the encoded amino acid sequence. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)).

Without sufficient guidance, determination of those nucleic acids having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rgh  
12/21/2008

/Richard G Hutson, Ph.D./  
Primary Examiner, Art Unit 1652